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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,042	01/30/2007	Koo Lee	1599-0325PUS1	6361
2292 7590 11/12/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER BASQUILL, SEAN M				
ART UNIT 1613		PAPER NUMBER		
NOTIFICATION DATE 11/12/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/579,042

**Applicant(s)**

LEE ET AL.

**Examiner**

Sean Basquill

**Art Unit**

1613

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- \_\_\_\_\_ Paper No(s)/Mail Date 23 Aug 2010

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-20 have been cancelled, and new Claims 21-27 have been entered for examination. Applicants are reminded that the invention they have elected to prosecute in this application contains a piperidine core structurally and chemically distinct from the pyrrolidine compounds falling within the scope of the instant claims. Applicants are advised to revise the language of Claim 1 to reflect their election of a pyrrolidine core (where variables M and N are each 2).

### ***Previous Rejections***

2. Applicants' arguments, filed 23 August 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112 First Paragraph – NEW MATTER***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Newly added Claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an actual invention, not merely an indication of a result that one might achieve if one made that invention. See, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984) (holding that a claim was not adequately described because the specification did ‘little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate’). This matter is of particular importance in the evaluation of claims drawn to a chemical genus which identifies a core compound bearing variable substituents. It has been held that “a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification...demonstrates that the applicant has invented species sufficient to support a claim to a genus” with such breadth. *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 94 USPQ2D 1161, 1171 (Fed. Cir. 2010). An adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties of species falling within the genus sufficient to distinguish the genus from other materials. *Id.*, quoting *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

However, merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species. *Ariad*, 94 USPQ2D at 1171. 35 U.S.C. 112, first paragraph, requires a description of the invention that “clearly allow[s] persons of ordinary

skill in the art to recognize that the inventor *invented* what is claimed.” *Ariad* at 1172, quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (1562-63) (Fed. Cir. 1991) (emphasis added). A sufficient disclosure is one which reasonably conveys to one having ordinary skill in the art that the inventor had possession of the claimed subject matter as of the filing date of the application in question. *Vas-Cath*, 935 F.2d at 1563. The description must reasonably describe the invention, not simply indicate a result which one might achieve if one actually made the invention. *Eli Lilly*, 119 F.3d at 1568. To properly evaluate whether an applicant has complied with the written description requirement therefore requires an analysis of whether the skilled artisan would recognize, from the description provided, the applicants were in possession of sufficient compounds representing the full breadth of diversity of the genus claimed.

Here, applicants have claimed an extraordinarily large genus of chemical compounds bearing an N-keto substituted piperidine core, as evidenced by the multiple variable substituents provided on the core compound of formula I, as well as the broad *Markush*-type groups describing the identity of a wide variety of chemical moieties which constitute the possible moieties for each variable substituent. Furthermore, within each of the delineated substituent groups, applicants have further indicated that each may further bear additional chemical moieties as substituents, giving rise to an exponentially larger group of possibilities for each of the distinctly named variables on the core compound. The size of the genus thus described is phenomenal, against which the applicants have offered evidence of having made only a relative handful of N-keto piperidine compounds falling within the genus as currently claimed. Specifically, applicants claim language directed to “heterocycle” and “spiro[2,5]octan” containing compounds of the instant invention are found to lack support in the disclosure as

originally filed. Per the definitions provided, as well as the lists of compounds made, the examiner can determine that of the possible "heterocycle" compounds falling within the broad definition of "heterocycle" applicable to the instant Claims, applicants have in fact only appeared to include heterocyclic moieties selected from morpholine, pyrrolidine, piperidine, furan, and tetrahydroisoquinoline ring systems. Likewise, applicants have demonstrated that they were in possession of no piperidine core compounds bearing a spiro[2,5]octan moiety. The particularly described compounds only represent a small portion of the compounds falling within the broad genus currently claimed, and in no way either represent the breadth of variable moieties which applicants have claimed, nor permit the skilled artisan to recognize that such claim breadth was actually in the applicants possession as of the time of filing the instant application.

***Allowable Subject Matter***

While no claims are allowable as currently presented, the examiner notes that both the species of the compound of formula I originally elected by the applicants, as well as considerable breadth of the genus claimed appear to be free of the art. The examiner, following applicants' replacement of the previous claims with the instant set, searched a number of piperidine core compounds of the instant claims, detailed in the attached STN search histories, and was unable to find art which either anticipated or rendered obvious the instant compounds. Applicants are therefore STRONGLY encouraged to contact the examiner to schedule an interview during which time appropriate modification to the claims currently presented may be discussed which will put the case in condition for allowance.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean Basquill/  
Examiner, Art Unit 1613

/Jeffrey S. Lundgren/  
Primary Examiner, Art Unit 1639